

510(k) Summary

Submitted by:

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DEC 05 2013

Date: Sept., 2013

Trade Name: Capella Dynamic Tilting, and Capella 45 variant, mechanical wheelchair

Common Name: Manual Wheelchair

Classification Name: Wheelchair, Mechanical

Regulation Number: 890.3850

Predicate Devices: PDG Inc. Fuze T20

Table of Comparison to Legally Marketed devices and effect of differences on safety and effectiveness

ITEM	Legally marketed: PDG Inc. Fuze T20	Future Mobility Healthcare Inc. Capella/Capella 45	Impact on safety and effectiveness
Indications for use	The PDG Fuze T20 is indicated for providing mobility to persons limited to a sitting position.	The Capella/Capella 45 is indicated for providing mobility to person limited to a sitting position.	The indicated use for devices is identical.
Manufacturer	PDG Product Design Inc.	Future Mobility Healthcare Inc.	n/a
K Number	K063736	K130788	n/a
Product Code:	IOR	IOR	n/a
FDA Product Class	I	I	n/a
Product Description	Dynamic tilt in space mechanical wheelchair which offers adjustability to redistribute the body weight for optimal positioning. The tilting is operated by the care-giver in the back handles of the chair. The Fuze T20 can accommodate different size occupants. The seat width and depth can be ordered in several sizes.	Dynamic tilt in space mechanical wheelchair which offers adjustability to redistribute the body weight for optimal positioning. The tilting is operated by the care-giver in the back handles of the chair. The Capella/Capella 45 can accommodate different size occupants. The seat width and depth can be ordered in several sizes.	All devices are designed with similar functions and the Capella/Capella 45 has no features that impact the safety and effectiveness of the predicate devices.
Intended surface for the operation	To be operated on all surfaces except rough surfaces	To be operated on all surfaces except rough surfaces	Unites are intended for same surface of operation
Safety Characteristics	Spring return push to lock wheel lock, anti-tippers	Spring return push to lock wheel lock, anti-tippers	All have the safety requirements for a mechanical wheelchair. This includes anti-tipper

			fixtures, wheel locking mechanism and a rigid body frame for resistance to fatigue, shear, as well as impact forces. The Capella/Capella45 has been designed and tested according to the ANSI/RESNA WC/Vol.1. All results are satisfactory and meet the standards indicated from ANSI/RESNA WC/Vol.1
Performance / Function			
Overall function and physical characteristics	The Fuze T20 is constructed of a rigid, aluminum frame with anti-tippers and the ability to tilt and manual recline. Depending on the seat depths, it has a capacity to support a human weight of 250lbs. One gas spring is used to lift and decline the seat and back to the tilting positions. The gas spring is connected by cables to levers on the push bar so that it can be locked and unlocked by the caregiver.	The Capella/Capella 45 is constructed of a rigid, aluminum frame with anti-tippers and the ability to tilt and manual recline. Depending on the seat depths, it has a capacity to support a human weight of 350lbs (250lbs Capella45). One gas spring is used to lift and decline the seat and back to the tilting positions in the Capella 45. And the Capella uses two gas springs. The gas spring(s) are connected by cables to levers on the push bar so that they can be locked and unlocked	The Capella has the same overall function and physical characteristics of a mechanical tilt in space wheelchair. It uses two gas cylinders to tilt the user with the controls located on the stroller bars. The Capella 45 similarly uses just one gas cylinder .

		by the caregiver.	
Tilt	20 deg	17deg Capella, 44 deg Capella 45	All devices have tilt capability. The resting state for the static stability test has been performed on all to indicate that the tilt does not create any stability problems.
Fixed recline	0 to 30 degrees	-7 to +21 degrees (28 degrees)	All devices have similar degree of fixed recline capability of up to 30 deg. And 28 deg. Respectively. The standard chair resting state is at +7 deg recline.
Seat width	13-20"	16-24"	No impact on safety and effectiveness. Test results are satisfactory.
Seat depth	15-20"	15-20"	Seat depth is similar and no impact to safety. Test results are satisfactory.
Seat-to-floor height	13-20" (front)	13-19" (front)	Wheelchairs are comparable in height and the difference should not have a bearing on safety and effectiveness.
Adjustable arm heights	10 to 14"	9.5 to 14"	This does not have an impact on effectiveness nor safety.
Front riggings	70 and 90 deg	60,70,80,90 deg	No impact on safety and effectiveness
Back post heights	20 and 25"	19" and 24"	No impact on safety and effectiveness
Rear wheel sizes	12,16,20,22,24	16,20,22,24	Various sizes are offered depending on end users preference. Each wheel size has

			been evaluated by Future Mobility for stability and strength with satisfactory results
Caster Sizes	5.6, or 8"	5.6, 7, or 8"	Various sizes are offered depending on end users preference. No impact on safety as each caster size has been evaluated by Future Mobility.
Chair width	For 12 and 16" rear wheels seat width is +9.5" for 20,22,24" rear wheels seat width is +10.75"	Seat width +10.75"	Does not have any impact to effectiveness. Safety has been evaluated to be satisfactory
Chair length	28" no riggings	31" no riggings	No impact on safety and effectiveness
Overall length	42"	45"	No impact on safety and effectiveness
Maximum human support weight	250lbs	350lbs (Capella) 250lbs (Capella45)	All chairs passed safety, stability, fatigue and strength tests.
Overall function and physical characteristics	The Fuze T20 is constructed of a rigid aluminum frame with anti-tippers and the ability to tilt and manual recline. It has a capacity to support a human weight of 250lbs	The Capella (and Capella45) is constructed of a rigid aluminum frame with anti-tippers and the ability to tilt and manual recline. It has a capacity to support a human weight of 350lbs (250lbs Capella 45)	All have the same overall function and physical characteristics of a mechanical tilt in space wheelchair.
Materials	Fuze T20 material meet the California Technical Bulletin CAL177 standard for flame retardant.	The material used on the Capella/Capella45 back rests and seat cushions meet the California Technical Bulletin CAL177	Both wheelchairs meet the flammability standards of CAL 177. No impact on safety and effectiveness.

		standard for flame retardant.	
Prescription use or over the counter	Over the counter	Over the counter	No impact to safety and effectiveness
Gas spring	The Fuze T20 utilizes a single centre positioned locking gas spring to operate the lift and decline of the seat.	The Capella utilizes two locking gas springs in tandem parallel configuration to operate the lift and decline of the seat. The Capella 45 utilizes a single centre positioned locking gas spring to operate the lift and decline of the seat.	No impact to the safety and effectiveness.

The rationale of declaring the Future Mobility Healthcare Capella wheelchair is substantially equivalent to the above predicate devices is based on the following:

- ✓ Same Indications for use: providing mobility to persons limited to a sitting position.
- ✓ Similar key design technical characteristics- the Fuze T20 and Capella are mechanical wheelchairs which have technical similarities.
- ✓ The Fuze T20 and Capella Dynamic tilt, and Capella 45, wheelchairs are manually operated, self propelled mechanical wheelchairs, and may also be used as attendant propelled transport devices. They consist of aluminum frames for use by patients weighing up to 250 lbs and 350 lbs, respectively.

Conclusion:

Future Mobility Healthcare Capella Dynamic Tilt mechanical wheelchair was developed in accordance with ISO 7176, parts 1, 5, 7, 8, 11, 13, and 15. It is the conclusion that the Future Mobility HealthCare Capella wheelchair is safe and effective, as well as substantially equivalent to the legally marketed device identified as the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 5, 2013

Future Mobility Healthcare
c/o Abdulsamad Panchbhaya,
President and CEO
3223 Orlando Drive
Mississauga, ON L4V 1C5

Re: K130788

Trade/Device Name: Capella Dynamic Tilt and Capella 45
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair
Regulatory Class: Class I
Product Code: IOR
Dated: October 18, 2013
Received: October 18, 2013

Dear Abdulsamad Panchbhaya:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130788

Device Name: Capella Dynamic Tilt and Capella 45

Indications For Use:

The Future Mobility Healthcare Inc. Capella wheelchair is intended to provide mobility to persons limited to a sitting position.

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Joyce M. Whang -S